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MEMORANDUM

TO: Commissioners

FROM: Eileen Fleck EF.
Chief, Acute Care Policy and Planning

DATE: April 17, 2014

RE: Staff Recommendation for Proposed Permanent Regulations: State Health Plan for Cardiac Surgery and Percutaneous Coronary Intervention Services (COMAR 10.24.17); Analysis of Comments Received

Maryland Health Care Commission (MHCC) staff is requesting that the Commission adopt as proposed permanent regulations a replacement COMAR 10.24.17: State Health Plan Chapter for Cardiac Surgery and Percutaneous Coronary Intervention Services ("Chapter"). A draft Chapter was posted for informal public comment on September 30, 2013. Twenty-four individuals or organizations commented on this early d raft. A copy of these informal comments is available on the MHCC web site[1]

Commission staff revised the draft Chapter based on these informal comments and submitted the revised draft Chapter to the Senate Finance Committee and the House Health and Government Operation Committee, on November 19, 2013. Staff received comments from each committee, as well as additional unsolicited comments. A copy of these comments is available on the MHCC website.[2]

A summary of the comments received on the cardiac surgery regulations and Staff's response to these comments is presented first, followed by a summary of the comments received regarding the PCI regulations and Staff's response to these comments. Staff has noted which changes were made in the draft regulations sent to the legislative committees and which

[1] http://mhcc.dhmh.maryland.gov/shp/Pages/Comar102417_Comments.aspx.
[2] http://mhcc.dhmh.maryland.gov/shp/Pages/Comar102417_Legislative_Comments.aspx.

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comments were addressed subsequently. Attached is a copy of the draft proposed regulations that staff recommends the Commission adopt as proposed permanent regulations (Appendix 1).

Staff Response to Comments Received on Draft Cardiac Surgery Regulations

.02 Introduction

E. Effective Date

Commission staff received comments from Dimensions Healthcare System (Dimensions) and the University of Maryland Medical System (UMMS) requested that it be made clear that standards are prospective only and that data collection will be required only going forward from the final date of regulations. In contrast to Dimensions and UMMS, Anne Arundel Medical Center (AAMC) commented that new standards should apply to a pending Certificate of Need (CON) project.

Staff Response

Staff concludes that no changes are required to clarify the effective date of the regulation. With regard to data collection, under COMAR 10.25.04.02, the Commission has the authority to require collection on outcomes of cardiac surgery, such as the STS composite scores for hospitals with cardiac surgery services. The Commission will provide appropriate notification in the *Maryland Register*.

Commission staff disagrees that pending projects should be subject to the new regulations. Projects that were prepared and filed in 2013 under the existing standards would potentially be affected. They have already begun the CON review process and are projects that, essentially, are hospital replacement and relocations, not projects being proposed for any reasons material to the hospital's cardiac surgery programs. It would not be fair or reasonable to impose this change in the review process.

.03 Issue and Policies

Policies and Other General Comments

Commission staff received comments supporting the policies included in the Chapter from Johns Hopkins Medicine, Doctors Community Hospital, and St. Agnes Hospital. Yuri Deychak, M.D. specifically commented that Policy 3 is very important, and a statewide public education program would be a good idea. However, MedStar Health (MedStar) commented that this section does not sufficiently address key environmental changes such as the decreased utilization of cardiac surgery and hospital payment policy changes. MedStar commented that the effect on decreased utilization of cardiac surgery should be discussed with respect to the impact on access, quality, efficiency, and financial viability. With regard to payment policy changes, MedStar expressed concern about the financial viability of sustaining programs with only 200 cases per year. Peter Horneffer, M.D. commented that the reference to "providers of PCI services" in Policy 5 is ambiguous.

Staff Response

Staff agrees that access, quality, efficiency, and financial viability are important factors to consider before approving new cardiac surgery services. These factors will be part of CON evaluation of a proposed new cardiac surgery programs. Staff also notes that the CAG considered issues of quality in setting the volume standard for a new program, and it recommended that the financial impact on existing providers be considered in CON reviews. Staff believes that the core principles of specialization and regionalization have been preserved. Only one new program in each of the four health planning regions may be added at a time, and if a new a new program is approved, no new programs may be considered in that region for three years after the new program is operational. The SHP chapter also notes that closure of a program does not in itself justify a new program. The SHP chapter also emphasizes that impact on other programs is a strong consideration for both new and relocated programs, whether the impact is volume, financial viability, or program quality.

The Chapter's inclusion of 200 cases per year as the minimum acceptable cardiac surgery case volume is based on the CAG's conclusions, which in turn are based on literature regarding the relationship between volume and outcomes. CON review criteria require consideration of financial viability and impact on other providers, as well as the forecast for cardiac surgery utilization. Staff recommends no changes to address MedStar's concerns because these criteria are sufficient to address MedStar's concerns regarding changes in hospital payment policies.

With regard to Dr. Horneffer's concern, Staff changed the reference from "provider" to a hospital, before submitting revised draft regulations to the legislative committees.

.03 Specialized Hospital Services

Commission staff received comments from AAMC, Adventist HealthCare (AHC), Johns Hopkins Medicine, MedStar Health, and UMMS regarding the proposed changes to the health planning regions. MedStar Health, AHC, and Johns Hopkins Medicine requested additional explanation for the proposed regions. AHC asked why the District of Columbia is included for the Metropolitan Washington region and not states that border other parts of Maryland. UMMS commented that the planning regions should not be changed and stated that the change creates distinct and separate health planning regions.

AAMC stated that the same factors that led to putting the Upper Shore counties together in the same region as Anne Arundel County would support the creation of a fifth planning region.

AHC commented that there is no discussion of planning regions by the Maryland Institute for Emergency Medical Services Systems (MIEMSS) for ambulance transport and planning regions. MedStar Health also commented that there should be a formal mechanism to ensure consistency and coordination of the regulations and policies between the Commission and MIEMSS. MedStar further stated that the geographic coverage and diversity of the new Baltimore/Upper Shore Region may have significant implications for redistributing programs and geographic access.

Staff Response

Staff relied heavily on utilization patterns for cardiac surgery in creating the new proposed health planning regions, as well as geographic proximity. The District of Columbia (DC) is included in the Metropolitan Washington region because a relatively high volume of Maryland residents use hospital facilities in the District of Columbia for cardiac surgery. This observed pattern is not indicative of a shortage of available and accessible facilities in Maryland. It reflects that two Maryland jurisdictions, with a population of approximately 1.8 million persons, border DC and those counties historically developed as suburbs and exurbs of DC. Excluding DC from the regional health planning for cardiac surgery services would create unbalanced regulatory oversight. It would also be inconsistent with the SHP chapter used by MHCC for cardiac surgery for decades. Finally, detailed data is available regarding patient origin for DC hospitals.

With regard to incorporating other bordering areas of other states in the SHP, levels of cross-migration for cardiac surgery services is too low to be material. This is not the case with DC.

Commission staff disagrees that a fifth planning region without a current provider of cardiac surgery services should be created. It would suggest that MHCC has already decided that a new program should be added rather than using forecasts for regions that actually align with the catchment areas that existing cardiac surgery programs have established.

With regard to AHC's concern about the relationship of the proposed planning region with MIEMSS ambulance transport and planning regions, MIEMSS did not on the new planning regions. Furthermore, redefining the health planning regions does not change the supply and distribution of cardiac surgery programs or emergency medical transport providers. Staff also concludes that the standing advisory committee for cardiac surgery and PCI, which will include a MIEMSS representative, will promote the necessary communication and coordination between MHCC and MIEMSS.

There is no direct impact on the geographic access or distribution of programs that is implied by the regions used in forecasting. No plan for redistribution of programs is included in the Chapter. The primary consideration for the evaluation of new programs (cardiac surgery or PCI services) identified in this draft is the service area of the applicant hospital regardless of the health planning region boundaries used in forecasting demand.

Although UMMS expressed concern that the changes to the planning regions create distinct and separate health planning regions, the borders of regions are not used as strict dividing lines for the evaluation of projects. The health planning region forecast of demand for cardiac surgery is not rigidly used to evaluate projects. This is explicitly addressed in the draft Chapter. It specifically provides that the impact on hospitals in adjacent health planning regions will be considered in CON reviews.

Specialized Hospital Services—Additional Comments

In addition to commenting on the proposed health planning regions, UMMS recommended deleting language stating that "the public is best served if a limited number of hospitals provide specialized services to a substantial regional population base." UMMS also

suggested that limiting the number of programs is inconsistent with the Clinical Advisory Group's (CAG's) preferred strategy of focusing on the quality of individual programs.

Staff Response

Staff has received comments supporting this language and requesting that MHCC take additional steps to promote the principles of regionalization for cardiac surgery services. Staff continues to conclude that the draft Chapter provides a reasonable balance considering the divergent views received on the question of what the "correct" or "optimal" number of cardiac surgery programs should be in Maryland. The draft Chapter continues to be based on many principles that have long been used for regulatory oversight in Maryland, and the referenced language noted by UMMS is directly informed by those principles. The language is also consistent with the clinical guidance given by the CAG. The CAG recommended 200 cases per year as the minimum acceptable cardiac surgery case volume. . The CAG did not make any recommendations on the specific issue of whether Maryland should promote program growth or seek to limit the number of programs.

Cost of Care

Staff did not receive comments on this section. However, staff updated this section to reflect that, in January 2014, the Health Services Cost Review Commission reached agreement on a new waiver model. At the time the regulation was drafted, an agreement had not yet been reached.

Access to Care

AAMC commented that there is no acknowledgement or discussion of equity of access. AAMC also stated that adequate access is only achieved by requiring some Maryland residents to travel out of state for cardiac surgery. AAMC proposed that the State should proactively address this issue by maximizing the utilization of in-state programs through the CON process.

Both AAMC and Johns Hopkins Medicine commented that access to cardiac services should be discussed in greater depth.

Staff Response

Staff concludes that patient decisions on where to seek care are driven by many factors outside the control of MHCC, such as insurance coverage and convenience, and the Chapter cannot maximize utilization of Maryland hospitals through the CON process. If MHCC ignores resources that Maryland residents prefer to utilize in the District of Columbia, the result may be additional costs to the health care system with no additional benefits for patients. Multiple hospitals in Maryland and the District of Columbia are part of a health care system that operates in both states, such as Johns Hopkins Health System and MedStar Health. There is not a strict separation of hospitals and health care systems based on state boundaries. For this reason, positive cooperative working relationships among all health care providers in both Maryland and the District of Columbia should be encouraged.

In response to the request from AAMC and Johns Hopkins Medicine that access to cardiac surgery be discussed in greater depth, Staff included additional discussion of access to cardiac surgery, noting that access to cardiac surgery appears adequate in Maryland.

Policy Guidance

UMMS commented that the CAG should continue to provide policy advice to MHCC. UMMS also stated that the scope and role should extend to focused reviews or program analysis.

Staff Response

Staff assumes UMMS intended to refer to the cardiac services advisory committee (CSAC) rather than the CAG. Staff recommends that focused reviews should be handled by outside parties without any conflicts of interest in evaluating Maryland hospitals. The CSAC will include several representatives of Maryland hospitals, and, therefore, cannot serve an unbiased role in focused reviews. Staff notes similar issues would arise with the CAG. In addition, the CAG would be expensive and difficult to maintain long-term. Staff will use appropriately qualified nurses or physicians for reviews of patient records and evaluations of the quality of care provided. Staff concludes that the draft Chapter, at this time, appropriately establishes the key components and procedural steps that will be used in focused reviews to assure competent review and opportunities for correction of problems.

.04 Commission Program Policies

A. Consideration of New Programs

(1) Cardiac Surgery

AAMC, Thomas Aversano, M.D., Johns Hopkins Medicine, and the Maryland Hospital Association (MHA) commented that quality measures were already chosen by the CAG and do not need to be chosen by the CSAC as stated in the proposed regulation. In addition, UMMS commented that the type of data on quality measures to be considered is unclear.

AAMC commented that quality reporting by existing facilities is not applicable to approval of a new program. In addition, Johns Hopkins Medicine, and Thomas Aversano, M.D. commented that an applicant has no way of demonstrating the quality of an existing program will not be negatively affected other than through an impact on volume.

AAMC, MHA, Johns Hopkins Medicine, and Thomas Aversano, M.D. all commented that the role of the standing committee is not supposed to be picking quality outcome measures.

MHA commented that a one-year time frame for developing and reporting on quality measures was not discussed by the CAG. In addition AAMC expressed concern that there would be an unreasonable multi-year delay in the consideration of a new cardiac surgery program.

Johns Hopkins Medicine and Thomas Aversano, M.D. expressed concerns about tying work of the CSAC to CON applications.

AAMC and MHA commented that there is a moratorium in effect because it is unclear when the rate setting system for Maryland hospitals will be deemed stable. Similarly, Johns Hopkins Medicine commented that the policy would block consideration of CON projects, and it

proposed that the costs and benefits of a new cardiac surgery program could be evaluated as part of the CON review process.

AHC commented that the Chapter eliminates the policy of only approving a new cardiac surgery program once every three years and that this change is not consistent with limiting the number of programs.

Staff Response

Staff agrees that two quality measures were chosen by the CAG for cardiac surgery services. These measures are the composite score for CABG cases from the STS quality rating reports for each twelve month rating cycle and the risk-adjusted all-cause thirty-day mortality rates.

In further considering the potential impact on the quality of another hospital's cardiac surgery program, Staff concludes that it would be difficult for an applicant proposing a new cardiac surgery program to address the potential impact on the quality of existing programs. This language was deleted, prior to submitting revised draft regulations to the legislative committees for review.

Staff concludes that the role of the CSAC includes choosing quality outcome measures. The quoted text cited by AAMC does not reflect the full discussion and recommendations of the CAG. Some performance measures were endorsed by the CAG, and these measures have been included in the Chapter, but the CAG also discussed the need for refining measures over time. It is the existing cardiac data advisory committee or the CSAC who would have primary responsibility for evaluating additional quality and performance measures.

In response to MHA's concern regarding the time allotted to the development of additional quality measures before a new cardiac surgery program will be considered, Staff has deleted the language. Staff also concluded that requiring reporting on the quality measures recommended by the CAG addresses the concerns raised by AAMC that a multi-year delay is possible, before any new cardiac surgery program is considered. These changes were made prior to submitting revised draft regulations to the legislative committees for review.

With regard to concerns about tying the work of the CSAC to CON reviews, Staff has addressed this concern by specifying that measures the CAG recommended will be the quality measures used. This change was made prior to submitting revised draft regulations to the legislative committees for review. Project reviews of CON applications are exclusively conducted by the Commission with no role by CSAC. However, the draft Chapter allows for the CSAC to advise the Commission on the development and use quality measures over time and make other policy recommendations.

To address the concern that a moratorium on new cardiac surgery program had been created, Staff changed the language cited to state that a hospital needs a budget agreement with the Health Services Cost Review Commission (HSCRC) regarding its rates. This addresses both the need for Staff to have adequate information to evaluate CON projects and the concern of

some hospitals that a moratorium had been created. This change was made prior to submitting revised draft regulations to the legislative committees for review.

The policy that AHC believed had been deleted, allowing a new cardiac surgery program only after allowing recently approved programs to get established, has been maintained. Staff recommends no change in response to this comment.

B. Closure of Programs

(1) Cardiac Surgery

Dimensions commented that the language stating that a cardiac surgery program will be considered for closure after it has been given an opportunity to correct deficiencies, under .04B(1)(d), should stand alone. UMMS further commented that a cardiac surgery program should be given an opportunity to correct deficiencies before closure is considered and proposed the same change. UMMS also commented that it is unclear whether a hospital that loses its CON for cardiac surgery would also lose its authority to provide PCI services. Lastly, UMMS commented that the Chapter needs to clarify who will evaluate conformance with performance standards under regulations.

Staff Response

Staff initially did not make the changes sought by Dimensions and UMMS in the draft sent to the legislative committees for review. However, Staff subsequently revised the language to clarify that existing programs will be given an opportunity to correct deficiencies before closure is considered. Staff clarified that a hospital that loses its authority to provide PCI services shall lose its authority to provide cardiac surgery services. Staff also added language to state that a hospital may continue to provide PCI services, if it loses its authority to provide cardiac surgery services, as long as it complies with the applicable requirements for a Certificate of Ongoing Performance. In addition, Staff clarified that independent auditors with clinical expertise will be the ones who evaluate the quality of patient care provided.

C. Relocation of Programs

(1) Cardiac Surgery

AHC commented that a discriminatory standard is being applied to a cardiac surgery program that seeks to relocate. AHC and UMMS stated that a hospital should just be holding a Certificate of Ongoing Performance based on current compliance or an approved plan of correction. UMMS also commented that the burden on a hospital for relocation of primary or elective PCI services is problematic because many hospitals are already exempt from obtaining a Certificate of Conformance by virtue of an existing PCI program, and the requirement relegates a hospital to the status of new, untested program.

Dimensions commented that the relocation requirements are redundant and should be deleted because a hospital with cardiac surgery must comply with the Certificate of Ongoing Performance standards already to maintain its program, regardless of whether it seeks to relocate.

AHC also commented that new language should be added to the Chapter that would allow a merged hospital system relocating cardiac services within the same jurisdiction to relocate services without a CON when the number of cardiac surgery programs would not increase.

Staff Response

The draft Chapter describes a process for regulatory oversight of cardiac surgery and PCI services that is similar to the approach currently used in CON reviews for other services. An acute care hospital is expected to demonstrate that it meets certain quality standards, even though it has been operating and would likely be allowed to continue operating, if a CON review had not been initiated by the applicant. The suggestion that having a plan of correction in place is adequate to allow a program to relocate is not acceptable. A hospital that does not successfully complete a plan of correction is at risk of losing its cardiac surgery program. Therefore, a hospital should not be allowed to relocate its cardiac services before the plan of correction has been completed and any performance problems resolved. Staff recommends no change in response to these comments.

With regard to UMMS' comments, staff notes that a CON is for a specific location. Moving to a different location means a hospital must justify services at the new location. Staff initially did not make changes to address UMMS concerns in the revised draft regulations sent to the legislative committees for review. However, Staff subsequently made changes to clarify which CON standards apply to a relocation project. Staff also notes that hospitals with only PCI services must obtain a new Certificate of Conformance should they relocate, while hospitals with cardiac surgery services must only demonstrate their compliance with Certificates of Ongoing Performance for elective and PCI services.

Staff concludes that due to the potential impact on other programs and costs for the health care system, the CON review process should still be followed in the circumstances described by AHC. Although the relocation of services may not increase the number of programs, it may not be cost-effective and could potentially jeopardize another hospital's cardiac surgery program. For this reason, Staff does not recommend the additional language sought by AHC.

.05 Certificate of Need Review Standards for Cardiac Surgery Programs

A. Cardiac Surgery Standards

(1) Minimum Volume

AAMC, Thomas Aversano, M.D., and Johns Hopkins Medicine commented that the volume threshold for a new program, 250 cases, is inconsistent with the CAG's recommendation of a minimum volume of 200 cases.

James Gammie, M.D. commented that the volume standard should be much higher to account for various subcategories of surgery, each of which should have a relatively high volume to maximize outcomes. He also cited studies on the volume-outcome relationship for aortic valve replacement (AVR) procedures and CMS requirements for a minimum total number of AVR prior to receiving approval from CMS to perform transcatheter aortic valve replacement

procedures (TAVR), a newer type of procedure. Dr. Gammie proposed that a minimum case volume of 500 cases is more appropriate, based on an assumption about the percentage of a hospital's cardiac surgery procedures that would likely be AVR (20%). MedStar Health also commented that the minimum volume standard is too low, noting that evidence suggests there is greater variability in quality in low volume programs than high volume programs between 600-700 cases per year. In addition, AHC commented that the standard for the end of the second year of operation should be slightly higher than currently proposed, 250 cases instead of 200 cases, because an applicant for a new program has to show a need of 250 cardiac surgery cases.

AHC commented that there is an application-specific health planning process, rather than regional planning in the draft Chapter, given the methodology in .05A(1)(d) of the draft proposed Chapter.

Staff Response

Staff changed the case volume standard from 250 cases to 200 cases to be consistent with the CAG's recommendation, prior to submitting the revised draft regulations to the legislative committees. Although MedStar Health and Dr. Gammie commented that the volume standard should be higher, the minimum volume of 200 cases was chosen based on the CAG's recommendation, which was informed by literature on the relationship between volume and outcomes. Although the studies and information provided by Dr. Gammie provide credible evidence for considering a volume standard for AVR procedures, it does not support changing the cardiac surgery volume standard to 500 cases. MedStar Health did not provide adequate evidence for Staff to recommend that the Commission depart from the CAG's recommendation with regard to the minimum volume for cardiac surgery programs.

Although AHC stated that a regional planning process is not being used, Staff disagrees with this conclusion. The Chapter limits the number of new cardiac surgery programs that may be approved in a health planning region to one at a time. In addition, after a new program is approved no new programs will be considered for the same health planning region until three years later. Staff also notes that the impact on other existing providers of cardiac surgery services is a factor considered in CON reviews. The utilization methodology, which allows an applicant to demonstrate why the methods and assumptions employed in the utilization projection are not reasonable as a basis for forecasting case volume, does not negate the policies and standards in the Chapter that are consistent with a regional planning approach.

(2) Impact

AAMC commented that the impact analysis required in .05A(2) is too burdensome, especially .05A(2)(c) which requires that an applicant demonstrate its proposed new program will not likely result in any additional loss of volume for a program with an annual volume of less than 200 cardiac surgery cases. AAMC also stated that the CAG recommendations do not support this requirement. Furthermore, AAMC commented that in the current Chapter the only basis for considering a new program is if the volume of a program drops below the minimum level, and the proposed Chapter reverses this approach without explanation.

AAMC stated that .05A(2)(a) and (b) should be limited to the health planning region in which the proposed program will be located. AAMC regards these standards as too burdensome

because the Baltimore/Upper Shore Region is adjacent to the other three health planning regions. AAMC noted that an affected hospital in an adjacent planning region can become an interested party in the review.

James Gammie, M.D. commented that .05A(2)(b) should specify that the cardiac surgery program is "in the health planning region or an adjacent health planning region" with an overlapping service area.

AAMC and MHA commented that only the impact on programs in Maryland should be considered. However, in contrast to AAMC, AHC commented that it is concerned about the volume impact of a proposed cardiac surgery program on existing cardiac surgery programs being too narrowly evaluated based on how a program defines its service area, rather than a regional plan. AHC stated that volume standards under .05A(2)(b) and (c) undermine language stating that the impact standard will take into account other providers in the health planning region or an adjacent health planning region.

MedStar commented that a new program is allowed to cause an existing program's volume to drop to 200 cases annually, a much lower standard than in the current Chapter, which is 350 cases. MedStar questioned this policy given the changes to the hospital rate setting system and the lack of evidence regarding unmet need.

AHC commented that the impact standard should be strengthened, with greater emphasis on the impact on quality at existing cardiac surgery programs. AHC suggested that language be added, similar to what is already included in the quality standard, with the addition of a sentence stating that a negative impact on quality "includes, for example, causing an existing cardiac surgery program to be at risk for not meeting the MHCC's quality standards and Certificate of Ongoing Performance for cardiac surgery or PCI." AHC also commented that the impact standard should also refer to "cardiac services" rather than cardiac surgery.

AHC also commented that the financial impact of the HSCRC waiver is not taken into account and that the standard should state that HSCRC will be asked to comment on both the financial feasibility and the financial impact on affected hospitals in a health planning region.

Staff Response

Staff revised the language to be more consistent with the volume standards used to evaluate existing programs and to give more consideration to programs that meet quality standards included in the Chapter, prior to submitting revised draft regulations to the legislative committees for review. Specifically, a proposed cardiac surgery program may not cause an existing program with two or more stars on the STS-ACSD composite star rating for CABG in two of the three most recent rating cycles to drop below 200 cases, if the program is currently performing 200 cases or more. If an existing program is performing between 100 and 200 cases, then the proposed program cannot drop below 100 cases as a result of a proposed new cardiac surgery program. The CAG's recommendations support this requirement because the CAG recommended 200 cases as the minimum threshold based on literature that suggests program quality often declines at volumes of less than 200 cardiac surgery cases annually. The

requirements in .05A(2) are necessary to protect existing programs from an excessive negative impact that could affect program quality.

Staff deleted the language in the current Chapter that allows a new program to be considered when an existing program drops below a minimum level because there is a longstanding decline in cardiac surgery statewide, and a program dropping below the minimum level may be the result of a decrease in the need for services. Therefore, the program may not need to be replaced. In addition, the current Chapter treats volume as the sole determinant of quality, assuming that a program below a certain volume threshold is not a quality program. Based on the CAG's feedback, the proposed Chapter focuses on both volume and quality measures as mechanisms for evaluating the quality of a program.

Staff concludes that an impact standard should not be limited to the health planning region in which a proposed program will be located. In some cases, a hospital may expect to serve a population where the majority of residents reside in an adjacent health planning region. Actual utilization patterns should not be ignored based on the borders of a health planning region. Staff agrees that an affected hospital can become an interested party in a CON review, and the impact on the affected hospital will be considered. However, the change proposed by AAMC would suggest that the impact of a new cardiac surgery program on hospitals outside the health planning region of the proposed project does not count. Staff recommends no change in response to these comments.

Staff concludes that it is unnecessary to add the language suggested by Dr. Gammie because referencing a hospital with an overlapping service area should encompasses hospitals that are affected by a proposed new cardiac surgery program in both the same health planning region and an adjacent health planning region.

Staff recommends no changes in response to suggestions that only the impact of a new proposed program on Maryland hospitals be considered. As previously stated, in response to similar comments from AAMC related to access to cardiac surgery services, MHCC has always concluded that hospitals with cardiac surgery services located in the District of Columbia should be given consideration in Maryland's health planning process. If Maryland ignores resources that Maryland residents prefer to utilize in the District of Columbia, the result may be additional costs to the health care system with no additional benefit for patients. It should also be noted that multiple hospitals in Maryland and the District of Columbia are part of a health care system that operates in both states, such as Johns Hopkins and MedStar. There is not a strict separation of hospitals and health care systems based on state boundaries. For this reason, positive cooperative working relationships between health care providers in Maryland and the District of Columbia should be encouraged.

Staff notes that AHC's concern that an applicant could define its service area was addressed through deleting references to the impact on hospitals with an overlapping service area in the revised draft sent to the legislative committees. Staff notes that additional changes to the need standard also make it clear that an applicant must conduct market share analysis and demonstrate the reasonableness of assumptions relied upon to define its proposed service area.

In response to MedStar's concern about allowing a greater volume impact on existing programs than currently allowed, when there is not evidence of unmet need, staff notes these concerns may be addressed through the CON application process. In addition, the minimum volume standard of 200 cases was set based on a recommendation of the CAG, and this recommendation was driven by a review of the literature suggesting that programs below 200 cases were often lower quality programs.

In response to AHC's proposed additional language, Staff notes that it has a broad meaning which is problematic. The phrase "at risk" may be interpreted as a lower bar than "unlikely to be negatively affected." This language proposed by AHC could make it extremely difficult for a new program to be approved, and it is not consistent with the impact criterion for CON reviews for other services.

In response to AHC's suggestion that the impact standard refer to "cardiac services," rather than cardiac surgery, Staff concludes that no change is needed. The impact on cardiac services generally is indirect and includes many services not regulated through CON.

In response to AHC's concern that changes to the rate setting system had not been taken into account and its suggestion that the regulations state that HSCRC will be consulted regarding the financial feasibility and impact of proposed new cardiac surgery programs, Staff notes that language was added to the draft submitted to the legislative committees stating that a hospital must have a population based budget agreement, a total patient revenue agreement, or a modified charge per episode agreement with HSCRC before its CON application to establish a cardiac surgery program will be considered. In addition, MHCC has historically worked with HSCRC staff to evaluate the financial viability of a CON project. Therefore, it is not necessary to include the proposed statements.

(4) Cost Effectiveness

AAMC commented that this standard is extremely broad and would apply throughout the State. It also stated that an applicant will not have the necessary information to quantify the financial impact on another program.

Staff Response

Staff concludes that the standard is not overly broad. An applicant must only analyze the financial impact on cardiac surgery programs from which the applicant projects to shift case volume to its proposed program. Staff also concludes that an applicant has the ability to estimate the financial impact on an affected program by calculating an average cost per case for the loss of volume based on its own program's estimates of revenue and expenses per case or by also seeking information from comparable cardiac surgery programs at hospitals in other states.

(6) Need

AAMC commented that requiring an applicant to demonstrate need in other health planning regions is unprecedented and inconsistent with the purpose of defining health planning regions.

After AAMC reviewed the revised draft regulations submitted to the legislative committees, AAMC did not submit additional written comments. However, AAMC provided verbal feedback directly to staff and at legislative hearings, stating that a service area definition based on referrals to surgery after diagnostic cardiac catheterization is problematic because patients may obtain diagnostic cardiac catheterization at a location with cardiac surgery, when a referral for cardiac surgery is likely. AAMC initially proposed returning to the language in the first draft posted for informal comment in September 2013. Both the Senate Finance and the House Health and Government Operations Committees supported this change.

Staff Response

Staff recommends no change in response to AAMC's comments regarding analysis of need in multiple health planning regions. Staff notes that the standard requires an applicant to demonstrate that a new program is needed based on projected demand for cardiac surgery by the population in its service area, and this approach is consistent with the requirements for an applicant seeking to add surgical services through the CON process. Staff also notes that because a proposed program may expect to serve a population that spans multiple health planning regions, the most accurate approach to health planning is to account for the entire population to be served, rather than ignoring half or more of the population that is proposed to be served. Staff also notes that there is a threshold of 20 percent for the need analysis described in the standard. An applicant is not asked to perform the need analysis described if less than 20 percent of the population to be served is from a different health planning region.

With regard to the service area definition and the references to it in Regulation .05A(6), Staff made changes to address the concerns AAMC raised after reviewing the revised draft regulations sent to the legislative committees. For example, an applicant is expected to include in its need analysis information on the number of patients referred for cardiac surgery following a diagnostic cardiac catheterization at the applicant hospital, but it is no longer the sole basis for defining the likely service area of a proposed new cardiac surgery program. An applicant is also expected to conduct a market analysis and demonstrate the reasonableness of the assumptions it relied upon in defining its proposed service area.

(7) Financial Feasibility

After revised draft regulations were submitted to the legislative committees for review, MedStar commented that language should be added to the impact standard stating that "an applicant shall quantify the proposed program's expected revenue per case operating at an efficient level, direct and indirect costs, and the optimal surgical volume required for the program to show a positive net gain."

Staff Response

In response to MedStar's concerns regarding the impact standard, Staff added a financial feasibility criterion. Staff concluded that the language proposed by MedStar Health pertains more directly to the financial feasibility of a new proposed program rather than the potential impact on other hospitals.

(8)Preference in Comparative Reviews

AAMC and Johns Hopkins Medicine commented that the preference standard in the current Chapter for an applicant with a proposed program that will include research, education, and training should be included in the proposed Chapter.

Staff Response

Staff made the proposed change in the revised draft regulations submitted to the legislative committees for review.

Other Comments Relevant to Section .05A

Dimensions commented that the Chapter should state that CON decisions will consider assessment of community need, not just utilization.

AHC commented that Staff should explain why certain language and standards included in the current Chapter were omitted. In one instance, AHC commented that deleting the standard is not consistent with limiting the number of cardiac surgery programs and should be maintained. Specifically, AHC cited the language stating that if the volume of cardiac surgery is declining then an applicant must show a benefit in terms of quality, access, or cost-effectiveness. AHC also commented that there is no explanation for deleting the requirement that a hospital with cardiac surgery services have a minimum average daily census of 100, excluding newborns (.05C(5) in the current Chapter). In addition, AHC commented that language related to requiring rate adjustment agreements has been removed and should be restored.

MedStar commented that prevention and outreach are addressed only marginally as a preference standard. MedStar recommended that the Chapter include stronger and more explicit policies promoting prevention and wellness.

Staff Response

With regard to Dimensions' comment, Staff concludes that an applicant will have an opportunity to raise the issue of community need through addressing the need standard and the current utilization methodology. Staff recommends that no change is necessary to address this comment.

Regarding AHC's comments, Staff concludes that no changes are needed to address its comments. The proposed Chapter includes criteria that require an applicant to demonstrate the need for cardiac surgery services and the cost-effectiveness of adding these services. Although the specific language cited by AHC has been deleted, similar standards are included in the proposed Chapter. Staff concludes that tying approval of a cardiac surgery program to the average daily census of the hospital is unnecessary given all of the other standards in the Chapter, including ones that require an applicant to demonstrate that a minimum volume of 200 cases will be achieved within two years. With regard to the requirement that a hospital have a rate adjustment agreement with HSCRC and agree to give up a minimum amount of revenue, Staff deleted this language because the rate setting system has changed, and the requirement is no longer applicable. A new approach to cost containment has been adopted.

With regard to MedStar's proposal that prevention and wellness be promoted more, Staff recommends no changes to address these comments. Staff expects that the financial pressure on

hospitals to reduce costs under a revised rate setting system will serve to motivate hospitals and health care systems to engage in outreach and prevention activities for cardiovascular disease to a much greater degree than achievable through CON regulation.

.07 Certificate of Ongoing Performance

A. General

After reviewing the revised draft regulations sent to the legislative committees, UMMS again expressed concern about the triggers for a focused review and the ability of MHCC to potentially shut down a program. Both the Senate Finance Committee and the House Health and Government Operations Committee recommended that, given the investment of the State in Prince George's County Hospital, consideration should be given to allow the Hospital three to five years to rebuild its cardiac surgery program. Both Committees also questioned the authority of MHCC to require a hospital to voluntarily relinquish its authority to provide cardiac surgery services based on the existing statute.

Staff Response

Staff added language specifically stating that a hospital with cardiac surgery services that has a pending application for a CON to relocate, prior to the effective date of the Chapter, may operate without a Certificate of Ongoing Performance. In addition, language was added to specifically state that if such a hospital receives a CON, then it will not require a Certificate of Ongoing Performance if it has been in operation fewer than 36 months. These changes should allow Prince George's County Hospital and Washington Adventist Hospital, which both have cardiac surgery services and pending CON applications for hospital replacement and relocation, adequate time to potentially meet the proposed performance standards.

Although legislators questioned MHCC's authority to require a hospital to voluntarily relinquish its authority to provide cardiac surgery services, there was strong support for revising the statute to give MHCC this authority. Senators Middleton, Kittleman, and Pugh sponsored a bill, SB 891, to authorize MHCC to require a hospital with cardiac surgery services to voluntarily relinquish its authority to provide cardiac surgery services when certain standards are not met. SB 891 was enacted during the 2014 legislative session and has been signed into law.

B. Cardiac Surgery

(2) Focused Reviews

UMMS commented that terms related to plans of corrections should be clarified. It stated that terms "approved plan of correction," "acceptable plan of correction," and "accepted plan of correction" are ambiguous and undefined. UMMS suggested that the term "acceptable" be stricken. UMMS also commented that there needs to be clarity on standards to be addressed in the plan, such as who will approve the plan and the process of arriving at an approved plan. Similarly, AHC expressed concern about the need for more details regarding focused reviews and the right of a hospital to appeal decisions of the Commission. Dimensions and UMMS requested that a hospital be given 60 days rather than 30 days to submit a plan of correction. Dimensions also proposed that a hospital should be given 30 days written notice that a focused review will be initiated. Dimensions had other suggestions for describing in greater detail the

process for a focused review. In addition, Dimensions suggested combining information on plans of correction, focused reviews, and closure in one section under Certificate of Need, Certificate of Conformance and Certificate of Ongoing Performance to assure clarity and consistency.

AHC also asked for confirmation as to whether MHCC bears the cost of focused reviews.

Staff Response

Staff made some changes to clarify the process for a focused review, before submitting revised draft regulations to the legislative committees. Staff eliminated the use of the word, "acceptable" and added a definition for "approved plan of correction" in response to UMMS's and AHC's comments. Staff concludes that 30 days written notice should not be required for a focused review and 60 days to submit a plan of correction also is excessive. A hospital should be tracking the quality of care provided and performance measures; in most cases a hospital should not be surprised by the need for a focused review. Staff initially did not make the changes proposed by Dimensions in terms of combining information under one section. However, Staff subsequently realized that combining information on plans of correction and focused reviews would eliminate the need to repeat the same language under multiple standards. Staff also realized that additional clarification regarding the process for a focused review was needed and concluded that allowing time for resubmission of a plan of correction is reasonable.

With regard to the cost of focused reviews and auditing hospitals' data, these costs will be paid through MHCC. Staff recommends no change in the regulation to address AHC's request for clarification.

(4) Quality

Although the Maryland Chapter of the American College of Cardiology is supportive of the external review requirement, comments from the Maryland Cardiac Surgery Quality Initiative (MCSQI), Johns Hopkins Medicine, and UMMS expressed concern about this requirement in terms of its cost and utility. James Gammie, M.D. expressed concern about how the external review process will be performed, the standards used as benchmarks, and the cost of such reviews. Keith Horvath, M.D. also commented that for external review, his recollection is that the CAG indicated the auditing process would be through an STS audit. Rather than relying on external review to evaluate the appropriateness of care, MCSQI expressed support for a multidisciplinary approach to discuss all treatment options with patients.

Both MCSQI and Johns Hopkins Medicine commented that a random review of five percent of cases would likely have a low yield. Johns Hopkins Medicine commented that data from STS reports on observed mortality to expected mortality is a very clear metric for quality and provides an objective easily reportable metric that is a surrogate for quality. UMMS noted that external review is burdensome and extremely costly, as much as $1,000 for a case. UMMS recommended a much more limited internal review, only ten randomly selected cases, with any case reviewed that is outside the standard of care submitted for external review and reported to MHCC. In addition, Keith Horvath, M.D. commented that the CAG did not recommend external review of five percent of cases for cardiac surgery.

Johns Hopkins Medicine, UMMS, and MCSQI expressed concern about the value of the standard for internal review of cardiac surgeons. Johns Hopkins Medicine commented that a review of 10 percent of cases or 10 cases is vague and "fails to point the reviewer at a measureable outcome." Johns Hopkins suggested that auditing the STS data is more useful and would verify the efficacy of the STS database. UMMS proposed internal review of only ten cases, and if care in any of the cases is deemed to be outside the standard, then the case will be externally reviewed. UMMS also noted that external review may be very expensive. Keith Horvath, M.D. also commented that the standard was not recommended by the CAG for cardiac surgery services, only for PCI services.

James Gammie, M.D. stated that risk adjusted mortality, as described in .07A(3)(b), should not be used because of wide confidence intervals and random changes in rank. Dimensions Health Care and MCSQI also commented on this standard. Dimensions proposed use of the national average, not statewide mortality average and expressed concern that half of all programs would likely be below the statewide average. MCSQI commented that a better definition for what constitutes exceeding the statewide average beyond an acceptable margin is needed. Instead of relying on the STS algorithm, MCSQI proposed benchmarking against the entire network of local peers.

MCSQI expressed concern about the confidentiality of patient information collected from internal and external review that may then reviewed by MHCC. MCSQI commented that details of the process need further delineation.

Staff Response

Staff deleted the requirement for external review of five percent of cardiac surgery cases and the specific requirements for internal case review before submitting draft regulations to the legislative committees for review.

With regard to Dr. Gammie's concerns on ranking cardiac surgery programs, Staff is not planning to rank programs based on mortality and can note the limitations of the statistical analysis in publications with mortality rates for multiple hospitals. The combination of the STS composite star rating and mortality rates together should alleviate some concerns about misinterpretation of the mortality rates. Staff notes that the proposed use of the composite star rating and mortality rates was recommended by the CAG. Staff expects the cardiac standing advisory committee can also revisit this issue and propose changes, if necessary.

Regarding Dimensions' comments, the CAG discussed using the national average and recommended that a statewide average be used because the data will be subject to greater auditing and may be more accurate potentially than national data. As a result, national data would not be the best source of comparison. Staff notes that half of all cardiac surgery programs will not necessarily be below the statewide average because a program must be outside the acceptable margin of error, which may be large enough that few or no programs are outside of it. Although staff had included a definition for "acceptable margin of error" in the definitions section, for the sake of clarity, staff moved the description to the regulations in the draft proposed regulations.

With regard to MCSQI's concerns regarding the confidentiality of patient information, Staff recommends no change. The existing language states that all individually identifiable patient information submitted to the Commission for the purpose described in this subsection shall remain confidential. Staff notes that it currently handles confidential patient information and has developed standards and procedures for preserving the confidentiality of this information.

(5) Performance Standards

Peter Horneffer, M.D. expressed concern about allowing a program with a one-star rating on the STS composite score to continue for two years before instituting a formal review process. In addition, Dimensions Health Care proposed that a hospital with two consecutive one star ratings be required to submit a plan of correction.

UMMS commented that .07A(5)(a)(i) should be revised to no longer state that a two star STS composite rating is the expectation for cardiac surgery programs. Instead, the standard should only state that four consecutive one star ratings is unacceptable.

MedStar commented that it will be difficult to shut down a program once it opens and expressed concerns about whether the Commission would enforce performance standards. MedStar commented that patients could be subjected to less than optimal care due to the protracted delay before shutting a program down.

Staff Response

In response to Dr. Horneffer's concern, Staff added language to state that a program with two consecutive one star ratings will be subject to a focused review. This change makes it clear that a cardiac surgery program will be evaluated carefully well before program closure is considered. This change was included in the draft regulations submitted to the legislative committees.

With regard to comments from UMMS, Staff concludes that no change is needed because the existing language is consistent with the CAG's discussion and recommendations regarding use of the STS composite star rating. Staff also notes that defining two stars at the acceptable level of performance is the basis for a focused review when a program has two consecutive one star ratings.

With regard to comments from MedStar Health, Staff concludes that it is unreasonable to assume that volume standards will not be enforced. In the past, the Commission has not had the direct statutory authority for enforcement that it has now. Staff also notes that information on the quality of programs will be publically available, so patients will have the ability to choose providers based on consideration of quality measures and volume of a provider, if desired.

(6) Volume Requirements

Dimensions commented that the standard seems to indicate that unless a program has a volume under 100 cases, then MHCC has no authority for a focused review.

Dimensions, Peter Horneffer, M.D., and MCSQI asked for clarification on what occurs when a hospital performs between 100 and 200 cardiac surgery cases. In addition, MCSQI proposed amending the wording in 6(a) to state that "a cardiac surgery program shall strive to maintain an annual volume of 200 or more cases."

MedStar Health stated that there should be minimum volume standards for cardiac surgeons.

Suburban Hospital commented that the provision in .07A(6) is not consistent with the CON awarded Suburban in July 2005. The condition states that if Suburban fails to meet a minimum of 200 cases, then it will close the program. Suburban stated that it expects the new Chapter will supersede the condition on its CON.

Staff Response

With regard to Dimensions' comment that MHCC appears not to have authority to conduct a focused review unless a program has a volume under 100 cases, Staff concludes that other language in the Chapter, under .07A(2) and .07A(5)(b), makes it clear that cardiac surgery programs may be subject to a focused review for reasons other than low volume. Staff also added language stating that a focused review will also be triggered by two consecutive one star STS ratings in the draft regulations reviewed by the legislative committees.

In response to the request for clarification on what occurs when a hospital performs between 100 and 200 cases, Staff intends for 200 cases to be a standard, not just a goal. For this reason, Staff recommends no change in response to the wording change proposed by MCSQI. Staff notes that a volume between 100 and 200 cases would not by itself trigger a focused review.

With regard to the comment that cardiac surgeons should be subject to minimum volume standards, Staff concludes that no change is needed. MedStar did not cite national guidelines or research studies as the basis for this recommendation. The CAG also did not recommend a volume standard for cardiac surgeons. MHCC generally strives for consistency with national guidelines and in the absence of such guidelines and without a recommendation from the CAG, it would not be appropriate to adopt a volume standard for individual surgeons.

Staff agrees with Suburban Hospital's comment that the volume condition on its CON for cardiac surgery services would be superseded by standards included in the draft regulations, if the Chapter is adopted as a final regulation.

.08 Utilization Projection Methodology for Cardiac Surgery

AAMC stated rather than using an average based on the year-to-year change in case volume for the previous six years, a linear regression should be used because the current methodology would not account for a recent upward trend in case volume. AAMC also commented on the definition of surgery which has implications for the utilization projection methodology. These comments are summarized and addressed under ".09 Definitions"

AHC commented that changes to the methodology are not adequately explained in terms of the draft Chapter's stated goals, and the Commission's precedent of limiting the number of programs. AHC also expressed concerned about projecting six years forward, and it proposed that additional age groups be considered. Specifically, AHC proposed that the cohort of persons age 65 and over should be subdivided.

MCSQI commented that the methodology chosen needs flexibility for future procedures. MCSQI noted that pacemaker and automated internal cardioverter defibrillator technologies are subject to the same quality and appropriateness concerns as other procedures and have not been addressed. MCSQI also mentioned transcutaneous aortic valve replacement (TAVR) and mitral valve interventions as other new technologies that should be addressed.

Staff Response

Although Staff initially changed the language as suggested by AAMC to reference an average year-to-year change in case volume based on a linear regression methodology, staff subsequently decided that it is better to use a simpler methodology that is easier to understand and validate. Rates are still calculated for each age group and the average of the percent year-to-year change is used, as proposed in the draft posted for informal comment in September, 2013.

With regard to AHC's request for further explanation of the changes in the need methodology and the Commission's precedent of limiting the number of programs, staff notes that the utilization methodology in the current Chapter serves a small role in limiting the number of programs by stating that the utilization projection represents the maximum projected need. The proposed methodology is very similar to the current utilization methodology and continues to have a relatively minor role in limiting the number of programs. In the proposed Chapter, as part of the required minimum volume and impact analysis, an applicant must either address the level of utilization in the relevant health planning regions or demonstrate why the assumptions in the utilization projection are unreasonable for forecasting volume.

In terms of the use of a six-year projection, staff notes that due to the lag in data availability, the current projection would be for 2018. In effect, demand is projected only about four years into the future. Given the large cost of establishing a new cardiac surgery program, Commission staff finds that looking beyond a two-year- period is likely to result in better planning decisions. Staff also notes that one advantage of using more years of historic data to project the future utilization of cardiac surgery is that it smoothes out dramatic increases and decreases in case volume that may not be realistic basis for future projections.

With the regard to AHC's suggestion that the 65 and over age group be subdivided, Staff expects that the proposed change will not make much difference in the projection of utilization and will add unnecessary complexity to the utilization methodology. Supporting information and research was not included by AHC.

With regard to MCSQI's comment, Staff notes that the Commission will strive to stay informed of updates in technology and the need to potentially update the utilization methodology for cardiac surgery. Staff will work with the cardiac data advisory committee, the cardiac

standing advisory committee, and stakeholders regarding additional performance and quality measures. For minor changes, such as updating the list of cardiac surgery codes once ICD-9 becomes effective, Staff believes that publishing timely notice in the *Maryland Register* is sufficient. Staff recommends no changes in response to MCSQI's comment.

.09 Definitions

Cardiac Surgery

AAMC commented that the definition of cardiac surgery was retained as including both open heart surgery and closed heart surgery, but the list of ICD-9 codes was excluded. AAMC recommended that specific codes be included. In addition, AAMC also commented that there is a need for flexibility to account for procedures that blur line between cardiac surgery and interventional procedures, such as transcutaneous aortic valve replacements (TAVR). AAMC noted that TAVR may only be performed by cardiac surgeons with cardiac surgery back-up. AAMC proposed that the following ICD-9 codes, which were created in 2011, be included in the Chapter: 35.05, 35.06, 35.08, 35.09, 35.97, and 37.37.

Staff Response

Staff initially revised the list of ICD-9 codes to include the codes referenced in the current Chapter, as well as the codes proposed by AAMC, before submitting revised draft regulations to the legislative committees for review. Staff also added language stating that the codes may be updated through publishing notice in the Maryland Register. However, Staff subsequently realized that two of the ICD-9 codes in the current Chapter for closed surgery often show up at hospitals without on-site cardiac surgery. In order to avoid an unintentional expansion of the scope of CON regulation, Staff recommends removal of the codes 37.12 and 37.31.

Focused Review

UMMS expressed continued concern about who would be conducting focused reviews and assuring that the auditor would be someone independent and qualified, after reviewing the draft regulations submitted to the legislative committees.

Staff Response

Staff modified the definition for a focused review to specifically state that it would be undertaken by "one or more independent auditors with clinical expertise."

Service Area

AAMC commented that the service area definition based on referrals to surgery is problematic because patients will obtain diagnostic cardiac catheterization at a location with cardiac surgery if a referral for cardiac surgery is likely. AAMC recommended that the definition for service area be deleted along with the standards that use the term.

The Senate Finance Committee and the House Health and Government Operations Committee both commented that they agreed with AAMC's request to change the language referencing "service area."

Staff Response

Staff initially did not change the definition for service area before submitting revised draft regulations to the legislative committees for review. However, the draft proposed regulations include a revised definition that addresses the concerns raised by AAMC. The service area for a proposed cardiac surgery program is no longer based on where patients received diagnostic cardiac catheterization that resulted in a referral for cardiac surgery. It is instead based on a specific type of cardiovascular services, either cardiac surgery, primary PCI, or elective PCI services.

External Review

Staff Response

With respect to external review, staff added a definition for external review to explicitly convey that such reviews must be objective and independent. The definition states that external review must be by clinical experts who are not affiliated with the hospital or health care system associated with the cases being reviewed. It also states that external review cannot be performed by physicians at one hospital in exchange for review by physicians at another Maryland hospital performing external review, unless the reviews are completed through a Commission-approved blinded system that involves four or more hospitals.

Staff Response to Comments Received Regarding Draft PCI Services Regulations

.03 Issues and Policies

Specialized Hospital Services

Frederick Memorial Hospital (FMH) objected to the change in service area, noting that it has always been included in the Western health planning region and aligns more closely with hospitals in the northern and western areas, not southern Maryland.

Staff's Response

Although FMH may align more closely with hospitals in the northern and western areas for some services, staff considered utilization patterns for cardiac surgery services specifically and found that the vast majority of Frederick County patients utilize services in the Washington Metropolitan region or the Baltimore Metropolitan region rather than the Western region. Staff continues to conclude that the health planning regions should reflect the region in which patients tend to seek cardiac surgery services. Frederick County residents do not seek cardiac surgery services in Cumberland, the only center for cardiac surgery in Western Maryland.

Cost of Care

Both UMMS and Doctors Community Hospital expressed concern that there would be a moratorium on new PCI programs due to language in this section.

Staff Response

The language in a subsequent section indicated that a delay was only intended for cardiac surgery programs. Staff deleted language in this section referencing a possible delay in

consideration of new PCI programs due to uncertainty regarding changes in the rate setting system, prior to submitting draft regulations to the legislative committees for review. The latest draft Chapter reflects the transitional planning underway by HSCRC for the new payment model adopted in January 2014.

.04 Commission Program Policies

(2)Elective PCI

Doctors Community Hospital commented that the hospital is not located in rural area and will likely not have the opportunity to provide PCI services, but cardiologists want to provide enhanced services. Doctors Community Hospital proposed that an avenue should be open to hospitals able to meet the quality and cost-effectiveness standards. Doctors Community Hospital also commented that an applicant should not have to offer two full years of primary PCI only.

Staff Response

The need for primary PCI services is an important criterion, and considering only quality and cost-effectiveness standards is not consistent with the approach taken for regulation of other CON services. The requirement to first perform only primary PCI cases during the first two years of providing PCI is included in the statute, with an exception for rural providers. This policy cannot be changed through a change in the PCI regulations. Staff also concludes that an applicant should establish a track record with emergency services before being allowed to provide services which are readily available at many different locations and can be scheduled in advance. Quality is an important consideration for expansion to elective PCI, unless there is a compelling reason to allow for both emergency and elective PCI to be established simultaneously, such as rural locations where access to emergency PCI is a critical issue. Staff recommends no change in response to the changes proposed by Doctors Community Hospital's comment.

(3) Primary PCI

UMMS commented that clarification on the review schedule for elective and pPCI programs is needed.

Staff Response

Staff changed the language in this section to state that a review schedule will be published at least annually, before submitting draft regulations to the legislative committees for review.

.06 Certificate of Conformance Criteria

A. Primary PCI Services

(2)Need

Dimensions commented that it is not clear how the volume requirement of 49 primary PCI cases will be enforced. Also with regard to enforcement, Dimensions commented that the right to appeal should be the same for CON and new PCI programs (Certificate of Conformance review). Both AHC and UMMS also commented that clarity on hospital rights is needed.

Staff Response

Staff has clarified how enforcement of this standard will be handled, as well as other standards for a Certificate of Conformance by adding language stating that a hospital that fails to meet the standards for a Certificate of Conformance shall agree to voluntarily relinquish its authority to provide PCI services, prior to submitting the draft regulations to the legislative committees for review. This language is consistent with the directive included in HB 1141(found at Health-General19-120.1G(2)(v)). Staff agrees that cardiac surgery and PCI programs should be treated similarly in terms of program closure. Legislation enacted in the 2014 session (SB891) and signed into law gives the Commission explicit authority to require that hospitals with cardiac surgery programs must agree to voluntarily relinquish their authority to provide cardiac surgery services if the hospital fails to meet applicable standards established by the Commission.

(6)Physician Resources

Yuri Deychak, M.D. commented that it should be clarified that physicians less than two years out of fellowship can perform PCI at hospitals without on-site cardiac surgery. He thinks hospitals should have discretion to decide, rather than having a restrictive standard.

Staff Response

Staff deleted the standard prior to submitting the draft regulations to the legislative committees for review.

B. Elective PCI Services

(1)Need

Carroll Hospital Center (CHC) commented that the .06B(1) standard suggests that a hospital cannot get a Certificate of Conformance for elective PCI unless it can demonstrate that it cannot provide primary PCI without elective PCI services too. It suggested that need should be based on achieving 200 or more elective cases by the end of the third year, in keeping with the requirement under primary PCI. CHC commented that the standard is too subjective.

Doctors Community Hospital also commented that the policy assumes that the only reason to allow elective PCI is to assist with the cost of providing emergency PCI and suggested that an avenue should be open to hospitals able to meet the quality and cost-effectiveness standards, as was noted with regard to Section .04A(2), Elective PCI.

MedStar commented that there should be a need methodology for elective PCI services, without specifically citing this section of the regulations.

Staff Response

Staff concludes that CHC's interpretation of the standard at .06B(1) is not consistent with the draft language. The standard provides that "[t]he hospital must demonstrate that its proposed elective PCI program is needed to preserve timely access to emergency PCI services for the population to be served." A hospital must show that providing primary PCI is essential. This may be done through evaluating the distance to the nearest alternative providers of primary PCI

and travel times by emergency vehicles for residents in the existing or proposed service area. Staff recommends no change to address CHC's comment.

Commission staff agrees that cost effectiveness matters, but it is secondary after establishing that need for a service exists. Staff recommends no change in response to Doctors Community Hospital's comment.

With regard to the suggestion that a need methodology for elective PCI services should be added, staff notes that it does not have the information required for a utilization projection of elective PCI services. NCDR CathPCI data from all hospitals with PCI services in the District of Columbia is needed for this. Staff will explore obtaining this data and believes that development of a utilization projection in a future iteration of the Chapter is warranted. In addition, staff has concluded that another factor may be more relevant in determining whether elective PCI services should be added to an existing primary PCI program or whether a new program with both elective and primary PCI services should be allowed, that is, whether there is an access problem for primary PCI services.

(2) Volume

Johns Hopkins Medicine and Thomas Aversano, M.D. noted that the standard at .06B(2) refers to a three-year timeframe to reach 200 PCI cases, and their understanding is that the standard is two years.

Doctors Community Hospital commented that the volume standard of 200 PCI cases should apply to all hospitals, with preference given to applicants that can demonstrate quick achievement of this and continue to meet and exceed the volume standard.

Staff Response

In response to the comments from John Hopkins Medicine and Dr. Aversano, staff changed the standard to refer to two years rather than three years, before submitting draft regulations to the legislative committees for review.

With regard to the comment from Doctors Community Hospital, staff concluded that no change is needed. There are multiple factors that should be considered and volume is just one important factor to be considered.

(3) Financial Viability

St. Agnes Hospital (St. Agnes), LifeBridge, and Doctors Community Hospital commented that they oppose the language in .06B(3) that allows the Commission to waive the volume requirement in subsection .06B(2), if the applicant demonstrates that adding an elective PCI program to its existing primary PCI program at its projected annual case volume will permit the hospital's overall PCI service to achieve financial viability. St. Agnes recommended that the proposed waiver from the volume requirement be deleted. LifeBridge and Doctors Community Hospital also recommended deleting language that would waive the volume requirements for the addition of an elective PCI program in some circumstances. St. Agnes proposed that, if the language is not deleted, then a waiver from minimum volume requirements should only be

available to programs in rural settings similar to the exception provided in primary PCI volume requirements.

Staff Response

The other criteria and standards for elective PCI services included in the Chapter assure that the language does not permit anyone with a primary PCI program to easily justify adding elective PCI without meeting volume expectations. Only programs serving a population without timely access to primary PCI at alternative locations will be given consideration for the addition of elective services and the draft Chapter still requires small program sites considered critical to provide needed access to primary PCI services to be viable.

Other Comments on Section .06

Clarification of Standards

MedStar commented that it is unclear how a Certificate of Conformance to establish a PCI program differs from a CON for cardiac surgery. MedStar noted that in both cases, CON standards in COMAR 10.24.10(A) must be addressed and need demonstrated. MedStar commented that the State Health Plan chapter needs to articulate differences in threshold standards.

Staff Response

MedStar's understanding is correct, and therefore Staff finds no clarification is necessary. In many cases, standards for hospital projects requiring a CON in COMAR 10.24.10, which was established as a set of standards applicable to a broad range of general acute care hospitals, will be appropriately applicable to considering PCI development projects, which will only be proposed by general acute care hospitals and will be subject to regulatory oversight through Certificates of Conformance.

Access to PCI Services

MedStar commented that expansion of access to PCI services may not improve outcomes, citing a specific research study. MedStar also stated that there needs to be additional data collection before approving an additional PCI program.

Staff Response

Staff believes that the weight of contemporary research still supports the notion that setting a benchmark for door-to-balloon times for primary PCI is an important objective for quality assurance. Door-to-balloon times will be affected by the geographic distribution of PCI program sites. Staff notes that the draft proposed Chapter specifically states that a new elective PCI program is only to be added when there is a need for access to emergency PCI services. This requirement should address MedStar's concern regarding the addition of unneeded PCI programs.

Preference for Existing Primary PCI Programs

UMMS commented that the draft regulations do not give favorable consideration to existing programs with emergency PCI services.

Staff Response

Staff has added language stating that a hospital that was providing emergency PCI services on January 1, 2012 will be given preference over another hospital that was not providing emergency PCI services on January 1, 2012, when the two hospitals have an overlapping service area and only one of the two PCI programs is needed to adequately serve the population in the primary service area of both hospitals. This change was included in the draft regulations submitted to the legislative committees for review.

.07 Certificate of Ongoing Performance

.07B(1); .07C(1); and .07D(1) Schedule of Reviews

UMMS commented that the criteria for renewing a Certificate of Ongoing Performance for less than five years should be in place.

UMMS also commented that it needs to be clearer when an acceptable plan of correction may be needed before a Certificate of Ongoing Performance will be granted. Similarly, LifeBridge Health commented that clarification was needed, and it recommended that language that reads "may require plan of correction" be strengthened.

Staff Response

Staff concludes that specifying the criteria for renewing a Certificate of Ongoing Performance for less than five years is unnecessary. It will not protect a program with poor performance that cannot correct its problems before the end of the Certificate of Ongoing Performance period or eliminate the potential for a focused review during the period of the Certificate of Ongoing Performance if potential problems are observed or suspected. Programs will be subject to ongoing monitoring, and if a problem is identified and a plan of correction is not successfully fulfilled, then a program may be required to relinquish its authority to provide the service before the end of a Certificate of Ongoing Performance cycle. Staff also recommends that the Commission first see how well using a renewal period of three or four years works, before potentially moving to a five-year window is considered.

Staff has clarified that a plan of correction must be completed before a Certificate of Ongoing Performance will be issued, and language was added to state that the Executive Director of MHCC may extend a hospital's current Certificate of Ongoing Performance if more time is needed to determine if the plan of correction has been completed. These changes were made prior to submitting revised draft regulations to the legislative committees.

.07C(2), and .07D(2) Focused Reviews

AHC commented that there should be a discussion of the process of removing a Certificate of Ongoing Performance when there is a disagreement on that course of action. AHC also asked for confirmation as to whether MHCC bears the cost of focused reviews.

UMMS also commented that there needs to be clarity on standards to be addressed in the plan, who will approve the plan, and the process of arriving at an approved plan. Similarly, AHC expressed concern about the need for more details regarding focused reviews, the right of a hospital to appeal a decision. Dimensions and UMMS requested that a hospital be given 60 days

rather than 30 days to complete a plan of correction. Dimensions also proposed that a hospital should be given 30 days written notice that a focused review will be initiated. Dimensions had other suggestions for describing in greater detail the process for a focused review. In addition, Dimensions suggested combining information on plans of correction, focused reviews, and closure in one section under Certificate of Need, Certificate of Conformance and Certificate of Ongoing Performance to assure clarity and consistency.

Staff Response

The statute adopted in 2012 clearly states that voluntary relinquishment is required for PCI services. A lengthy and expensive legal process for revocation of program authority, in which poorly performing programs would continue to treat patients, is not considered to be a satisfactory approach to performance-based regulatory oversight. The draft proposed Chapter shifts the emphases in the set of criteria and standards used by MHCC so that performance-based review is a more important factor in MHCC decisions. The draft Chapter outlines the key features of a fair and workable process for conducting focused review.

Initially, staff did not suggest changes to address AHC's comment. However, staff subsequently made changes to the description of focused reviews and the process for the development and approval of a plan of correction to address deficiencies identified. Staff concludes that these changes should minimize disagreement regarding the actions a hospital must take to correct deficiencies.

With regard to the cost of focused reviews and auditing hospitals' data, these costs will be paid through the Maryland Health Care Commission. Staff recommends that no change in the regulation is needed to address AHC's request for clarification.

Staff made some changes to clarify the process for a focused review, before submitting revised draft regulations to the legislative committees. Staff concludes that 30 days written notice should not be required for a focused review and that 60 days to submit a plan of correction also is excessive. A hospital should be tracking the quality of care provided and performance measures; in most cases a hospital should not be surprised by the need for a focused review. Staff initially did not make the changes proposed by Dimensions in terms of combining information under one section. However, Staff subsequently realized that combining information on plans of correction and focused reviews would eliminate the need to repeat the same language under multiple standards. Staff also realized that additional clarification regarding the process for a focused review was needed and concluded that it is reasonable to allow time for resubmission of a plan of correction that, when initially submitted is unacceptable, makes sense.

.07C(4) and .07D(5) Quality

Holy Cross Hospital (HCH) commented that all hospitals should be required to have a robust quality oversight program and represent that to MHCC, but HCH also is concerned that requiring disclosure of confidential peer review information, could have a chilling effect on physicians being open and cooperative. HCH proposed that instead hospitals should submit blinded data regarding performance by individual physicians, with number of cases, number of cases reviewed, and aggregate data, with opportunities for improvement and necessary actions

identified. It noted that the State would retain existing authority to obtain individual physician or patient level data if needed. Adventist Health Care also asked for confirmation that the chart review process would not interfere with the confidentiality protections afforded to hospital quality assurance processes.

The Maryland Chapter of the American College of Cardiology (Maryland ACC Chapter) expressed support for the external review requirements. It proposed raising the standard even higher than five percent for PCI services, up to ten percent. It also expressed support for the MACPAQ model of case review.

The Maryland ACC Chapter provided additional comments on the draft regulations submitted to the legislative committees for review. It proposed that external review should be conducted on quarterly basis, rather than annually. Delegate Nicholaus Kipke wrote a letter to MHCC supporting the proposed change of the Maryland ACC Chapter.

Staff Response

Staff recommends no change in response to HCH's comment. Key information may be missed if only summary information is provided. The Commission has experience handling confidential information and will take appropriate steps to assure that information is protected.

Staff's recommendation of five percent of cases for external review is consistent with the CAG's recommendation. Although ten percent may be more informative, the benefits and costs of external review need to be weighed carefully. Staff also supports the MACPAQ model as one approach to external review and support for this model was expressed by many members of the CAG. However, it was also decided that hospitals should be given flexibility in how to meet the external review criteria.

In response to the additional comments of the Maryland ACC Chapter recommending quarterly review, Staff conducted additional research and solicited feedback from hospitals. Based on this additional information, Staff recommends changing the regulations to state that semiannual reviews of cases for the preceding six months are required, rather than annual case review. Staff concluded that this change strikes the right balance between cost and quality oversight. Staff also is concerned that hospitals may not be able to interpret the results of quarterly reviews, given the volume of cases reviewed could be very small.

.07C (5) Patient Outcome Measures

Christopher Haas, D.O. had suggestions for an additional performance measures. He proposed that a program that falls below the 50th percentile of a particular comparative benchmark for appropriate use should be subject to a focused review. He also proposed that programs above the national average for the number of diagnostic catheterizations that result in no finding of obstructive disease should be subject to a focused review.

Staff Response

The proposed performance measures should be considered further by the cardiac data advisory committee and CSAC before including in regulations. The CAG did not discuss the proposed measure.

.07C(6) and .07D(7) Physician Resources

Dr. Deychak commented that a requirement for ten proctored cases may be excessive; five may be sufficient.

Staff Response

The standard is consistent with the current SHP standard, and it is not inconsistent with the CAG's recommendations. Staff concludes that no change is needed to respond to this comment.

.07C(4) and .07D(5) Quality

Dr. Haas and Dr. Deychak commented that patient records should be part of performance review, not just review of angiographic images.

UMMS commented that external review is burdensome and extremely costly. It stated that review of only one case may cost thousands of dollars. UMMS recommends internal review of 10 randomly selected cases and proposed that any case outside the standard of care will be submitted for external review. UMMS also suggested that any case below standard of care should be reported to MHCC.

FMH and AHC commented that external reviewer qualifications need to be clearly defined and included in the Chapter.

Staff Response

In response to the comments from Dr. Haas and Dr. Deychak, Staff added language stating that patient records should be part of case reviews, prior to submitting revised draft regulations to the legislative committees.

With regards to UMMS proposal to reduce the number of cases subject to external review, Staff concludes that no change is needed. Ten cases total may be too few for large programs with hundreds of cases. External review is essential for validating the results of internal review. Staff's recommendation is consistent with the CAG's recommendation.

With regard to the qualifications of external reviewers, Staff initially did not make changes. The regulations already referenced that hospitals must comply with standards for external reviewers established by MHCC to assure consistent rigor. However, Staff agrees that additional clarification is required and should be handled through consultation with the cardiac standing advisory committee. In addition, after submitting revised draft regulations to the legislative committees, Staff added a definition for external review that clarifies the reviewers must be independent. The reviewer cannot be physicians at another hospital in the same health care system, and other requirements have been included to assure that external review will be independent.

.07D(8) Volume

Dr. Deychak commented that a target of 11 STEMI cases, per current guidelines is fine, but it should not be a cutoff.

Staff Response

The standard is consistent with the current standard and CAG recommendations. Staff concludes no change is needed to address this comment.

Other Comments on Section .07

Timing of Reviews for a Certificate of Ongoing Performance

UMMS commented that it is unclear how long after a hospital receives a Certificate of Conformance for PCI that the hospital will be subject to review for a Certificate of Ongoing Performance.

UMMS commented that a hospital should also be clear that a hospital may "renew" its Certificate of Ongoing Performance before the expiration date.

Staff Response

Staff added language specifying the timing for a hospital to apply for Certificate of Ongoing Performance.

Standard practice for PCI waivers has been to handle renewal decisions before the expiration date of the waiver; Staff does not understand the source of concern for UMMS. Commission staff is aware that services should be continuously available and not shut down for a week or longer because a decision has not yet been made, even though a hospital's Certificate of Ongoing Performance has expired. However, action on a renewal request is dependent on a hospital's provision of timely and complete information to the Commission.

.09 Definitions

Primary PCI operator

Dimensions requested that the term "primary PCI operator" be defined.

Staff Response

Staff added a definition of the term as requested, prior to submitting revised regulations to the legislative committees for review.

Elective PCI

Dr. Deychak commented that the elective PCI definition could include patients suffering from an acute coronary syndrome.

Staff Response

Staff initially did not change the definition for elective PCI. No change was included in the draft given to legislative committees. However, staff subsequently included the change proposed by Dr. Deychak.